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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,909	10/01/2003	Harald Kropshofer	21388	8340
151 7590 04/18/2008 HOFFMANN-LA ROCHE INC. PATENT LAW DEPARTMENT 340 KINGSLAND STREET NUTLEY, NJ 07110				
EXAMINER VANDERVEGT, FRANCOIS P				
ART UNIT		PAPER NUMBER		
1644				
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04/18/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/676,909

Applicant(s)

KROPSHOFER ET AL.

Examiner

F. Pierre VanderVegt

Art Unit

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-33 is/are pending in the application.
- 4a) Of the above claim(s) 28-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claim 16 has been canceled.

Claims 1-15 and 17-33 are currently pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 17, 2008 has been entered.

Election/Restrictions

2. **Claims 28-33 stand withdrawn** from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 6, 2006.

Claim 15 has been REJOINED with the invention of Group I.

Accordingly, **claims 1-15 and 17-27 are the subject of examination** in the present Office Action and only to the extent that they read upon MHC class II peptides.

In view of Applicant's amendments filed January 17, 2008, no outstanding ground of rejection is maintained. The following represent new grounds of rejection.

Applicant's arguments with respect to claims 1-14 and 17-27 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-14 and 17-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1, 13, 14 and 27 are ambiguous and unclear in the recitation of “isolating antigenic peptides in femtomolar amounts.” The term “femtomolar” does not specify any specific amount, but is rather a term that can be associated with a concentration of a substance in a carrier.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-2, 7-12, 14, 19, 20, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalbacher et al (J. Chromatography [1991] 548:343-350; C34 on form PTO-1449 filed 12/8/2006).

Kalbacher teaches the isolation of antigenic peptides from human HLA-DR MHC class II molecules in femtomolar amounts (page 348, last two paragraphs and Figure 4 in particular). Kalbacher teaches the elution of the peptides from the complexes using “diluted” acid and the identification of the peptides via chromatography.

As stated in paragraph 3 supra, the term “femtomolar” is indicative of a concentration of a substance in a carrier, rather than a measurement of a quantity. While Kalbacher does not specifically teach the concentration of the eluate, it would be well within the purview of the artisan to elute antigenic peptides from MHC class II receptors at a wide range of concentrations.

5. Claims 1-3, 7-12, 14-15, 19, 20 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chicz et al (J. Exp. Med. [1993] 178:27-47; C12 on form PTO-1449 filed 10/1/2003).

Chicz teaches the isolation of antigenic peptides from human HLA-DR MHC class II molecules (see entire document, Abstract in particular). Chicz teaches the immunoaffinity purification of the

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complexes, the elution of the peptides from the complexes using “diluted” acid and the identification of the peptides via chromatography (Tables 1-6 and Figure 3 in particular). Chicz teaches a general method for the elution and identification of peptide antigens from MHC class II+ cells and exemplifies the method using transformed B cell lines. The B cells taught by Chicz inherently express MHC class I and therefore satisfy the metes and bounds of claim 15.

As stated in paragraph 3 *supra*, the term “femtomolar” is indicative of a concentration of a substance in a carrier, rather than a measurement of a quantity. While Kalbacher does not specifically teach the concentration of the eluate, it would be well within the purview of the artisan to elute antigenic peptides from MHC class II receptors at a wide range of concentrations.

6. Claim 4, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chicz et al (J. Exp. Med. [1993] 178:27-47; C12 on form PTO-1449 filed 10/1/2003) as applied to claims 2 and 16 above, and further in view of Arndt et al (EMBO J. [2000] 19(6):1241-1251; C20 on form PTO-1449 filed 10/1/2003).

Chicz has been discussed *supra*.

While Chicz teaches a general method for the elution and identification of peptide antigens from MHC class II+ cells, Chicz exemplifies the method using transformed B cell lines and does not specifically teach dendritic cells.

Arndt teaches the immunopurification of peptide-containing MHC class II complexes from B cells and immature dendritic cells (see entire document, Abstract in particular). Arndt teaches a similarity of antigen loading and presentation by the two antigen presenting cell types.

It would have been *prima facie* obvious to a person having ordinary skill in the art at the time the invention was made to examine antigenic peptide binding to dendritic cells in the same manner as Chicz teaches for B cell clones. One would have been motivated to use dendritic cells in place of B cells with a reasonable expectation of success by the teachings of Arndt that antigen processing/presentation is similar between the APC types and the desire to use isolated cells rather than cells of clonal lines in order to better study natural peptide processing *in vivo*.

Conclusion

7. No claim is allowed.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571)272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D. /PV/
Patent Examiner

April 14, 2008/David A Saunders/
Primary Examiner, Art Unit 1644